

National Cancer Institute
Institutional Review Board
AGENDA (*revised 9/1/15)
September 14, 2015
1:00 – 5:00 pm
10 CRC/3-1608

- 1. Review of Draft Minutes, August 24, 2015**
- 2. Announcements**
- 3. Old Business**
- 4. New Business**
 - Genomic Data Sharing Plan
- 5. Problem Report Forms**
- 6. Other Expedited Actions**
- 7. Continuing Reviews**
- 8. Amendment** 15C0150A, "A Phase I/II Trial of Topotecan with VX970, an ATR Kinase Inhibitor in Small Cell Lung Cancer" - Anish Thomas, PI
- 9. Amendment** 15C0093C, "Phase I/II Trial of PLX3397 in Children and Young Adults with Refractory Leukemias and Refractory Solid Tumors Including Neurofibromatosis Type 1 (NF1) Associated Plexiform Neurofibromas (PN)" - Rosandra Kaplan, PI
- 10. Amendment** 10C0219M, "A Phase I Trial of Lenalidomide and Radiotherapy in Children with Diffuse Intrinsic Pontine Gliomas and High-grade Gliomas" - Kathy Warren, PI
- 11. Amendment** 14C0175A, "A Phase 2, Multicenter, Single-arm Study of Moxetumomab Pasudotox in Pediatric Subjects with Relapsed or Refractory Pediatric Acute Lymphoblastic Leukemia (pALL) or Lymphoblastic Lymphoma of B-cell Origin" - Nirali Shah, PI
- 12. Amendment** 15C0040B, "A Phase II Trial of Mutation-Targeted Therapy with Sunitinib or Everolimus in Patients with Advanced Low or Intermediate Grade Neuroendocrine Tumors of the Gastrointestinal tract and Pancreas with or without Cytoreductive Surgery" - Electron Kebebew, PI
- 13. *Amendment** 14C0156E, "A Phase II Single Arm Pilot Study of the Chk1/2 Inhibitor (LY2606368) in Women with BRCA1/2 Mutation Associated Breast or Ovarian Cancer, Non-high Risk Triple Negative Breast Cancer, and High Grade Serous Ovarian Cancer at Low Genetic Risk"—Jung-Min Lee, PI
- 14. Initial Review** P152427, "Clinical and Laboratory Analysis of Familial Cancer" - Kathleen Calzone, PI
- 15. Initial Review** P152242, "Pilot Trial of Allogeneic Blood or Marrow Transplantation for Primary Immunodeficiencies" - Jen Kanakry, PI

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- 16. Initial Review** P152152, "T Cells Expressing a Fully-human Anti- CD19 Chimeric Antigen Receptor for Treating B-cell Malignancies" - Jim Kochenderfer, PI
- 17. Initial Review** P152347, "Prostvac in Patients with Biochemically Recurrent Prostate Cancer" - Ravi Madan, PI